PR 13-58

SPECIAL BULLETIN

OCTOBER 28, 2013

ATTN: ALL PARTICIPATING PROFESSIONAL PROVIDERS

MEDICAL POLICY UPDATES AND NEWS

OCTOBER AND NOVEMBER

Highmark Blue Cross Blue Shield Delaware (Highmark Delaware) is committed to keeping you informed of updates to our medical policies, guidelines and payment policies. This *Special Bulletin* includes information regarding new or updated medical and behavioral health policies, which reflect changes in medical technology, criteria for approving or denying services in various policies, and federal or Delaware medical policy requirements.

Highmark Delaware Medical Policies are available online via the Provider Resource Center, which is accessible through NaviNet® or from the *Providers* tab on our website, **www.highmarkbcbsde.com**. Once there, select *Medical & Claims Payment Guidelines* from the menu on the left-hand side. You can then search our Medical Policies by one (or a combination) of the following options: keywords, code or number.

NEWS

Peginesatide (Omontys) recalled by FDA

Highmark Delaware will no longer consider Peginesatide (Omontys) medically necessary due to a Food and Drug Administration (FDA) recall. The FDA has recalled Peginesatide (Omontys) due to reports of serious and sometimes fatal adverse hypersensitivity reactions, including anaphylaxis.

Peginesatide (Omontys) has been removed from Medical Policy Bulletin I-7, Erythropoiesis Stimulating Agents.

POLICY

Place of service designation included on additional medical policies

Highmark Delaware is including place of service designation on the following medical policies:

Policy #	Policy Topic	Place of Service	Effective Date
E-3*	Home Apnea Monitors	Outpatient	01/06/2014
E-9*	Gradient Compression Garments	Outpatient	01/06/2014

Policy #	Policy Topic	Place of Service	Effective Date
E-36*	Speech Generating Devices	Outpatient	01/06/2014
G-9*	Diagnosis and Treatment of Male Sexual Dysfunction	Outpatient	12/30/2013
G-16*	Chemotherapy Services	Inpatient/Outpatient	01/06/2014
I-7*	Erythropoiesis Stimulating Agents (Epoetin Alfa [Epogen, Procrit], Darbepoetin Alfa [Aranesp])	Outpatient	01/06/2014
I-27*	Certolizumab (Cimzia®)	Outpatient	01/06/2014
I-97*	Radium Ra 223 Dichloride for Treatment of Prostate Cancer	Outpatient	01/06/2014
L-28*	Tumor Markers	Outpatient	01/06/2014
M-7*	Electronystagmography (ENG) and Videonystagmography (VNG) Services	Outpatient	01/06/2014
M-54*	Thoracic Electrical Bioimpedance (TEB)	Outpatient	01/06/2014
O-24	Ankle-Foot/Knee-Ankle-Foot Orthosis	Outpatient	01/06/2014
R-6*	Single Photon Emission Computed Tomography (SPECT)	Outpatient	01/06/2014
S-36*	Removal of Skin Lesions	Outpatient	01/06/2014
S-81	Orthodontic Treatment of Cleft Lip	Inpatient	10/28/2013
S-146*	Percutaneous Vertebroplasty	Inpatient/Outpatient	01/06/2014
S-182	Carotid Angioplasty with Stenting	Inpatient	09/09/2013
S-197*	Manipulation Under Anesthesia	Outpatient	01/06/2014
X-54*	Cardiac Computed Tomography	Outpatient	01/06/2014
Y-11*	Lymphedema Therapy	Outpatient	01/06/2014
Z-3*	Hyperbaric Oxygen (HBO) Therapy	Outpatient	01/06/2014
Z-26*	Allergy Skin Testing	Outpatient	01/06/2014

* Typically an outpatient procedure which is only eligible for coverage as an inpatient procedure in special circumstances including, but not limited to the presence of a co-morbid condition that would require monitoring in a more controlled environment such as the inpatient setting.

Medical necessity criteria added for liver transplantation

Highmark Delaware is updating its coverage criteria for Liver Transplantation. The new guidelines will become effective on Jan.6, 2014.

- Hepatocellular diseases:
  - Alcoholic liver disease; or
  - Cryptogenic cirrhosis; or
  - Viral hepatitis (either A, B, C, or non-A, non-B); or
  - Idiopathic autoimmune hepatitis; or
  - Alpha-1 antitrypsin deficiency; or
  - Hemochromatosis; or
  - Non-alcoholic steatohepatitis; or
  - Protoporphyria; or
  - Wilson's disease; or
- Vascular disease:
  - Budd-Chiari syndrome; or
  - Veno-occlusive disease
- Inborn errors of metabolism
- Trauma and toxic reactions
- Miscellaneous:
  - Polycystic disease of the liver; and
  - Familial amyloid polyneuropathy; and
  - Portopulmonary hypertension (pulmonary hypertension associated with liver disease or portal hypertension) in persons with a mean pulmonary artery pressure by catheterization of less than 35 mm Hg; and
  - Toxic reactions (fulminant hepatic failure due to mushroom poisoning, acetaminophen); and
  - Trauma; and
  - Hepatopulmonary syndrome when the following selection criteria are met:
    a. Arterial hypoxemia (PaO2 less than 60 mm Hg or AaO2 gradient greater than 20 mm Hg in supine or standing position); and
    b. Chronic liver disease with non-cirrhotic portal hypertension; and
    c. Intrapulmonary vascular dilatation (as indicated by contrast-enhanced echocardiography, technetium-99 macroaggregated albumin perfusion scan, or pulmonary angiography).
- Liver transplantation may be considered medically necessary in patients with unresectable hilar cholangiocarcinoma.
- Liver transplantation is considered experimental/investigational in ANY of the following situations:
  - Patients with extrahepatic cholangiocarcinoma; or
  - Patients with intrahepatic cholangiocarcinoma; or
  - Patients with neuroendocrine tumors metastatic to the liver not identified above.

  A participating, preferred, or network provider can bill the member for the non-covered service.
- Potential contraindications for liver transplant recipients include, but are not limited to ANY of the following:
  1. Known current malignancy, including metastatic cancer not identified in any of the medical necessity criteria above; or
  2. Recent malignancy with high risk of recurrence; or
  3. Untreated systemic infection making immunosuppression unsafe, including chronic infection; or
  4. Other irreversible end-stage disease not attributed to liver disease; or
  5. History of cancer with a moderate risk of recurrence; or
  6. Systemic disease that could be exacerbated by immunosuppression; or
  7. Psychosocial conditions or chemical dependency affecting ability to adhere to therapy; or

8. Demonstrated patient noncompliance, which places the organ at risk by not adhering to medical recommendations; or
9. Potential complications from immunosuppressive medications are unacceptable to the patient; or
10. AIDS (diagnosis based on CDD definition of CD4 count, 200 cells/mm^3) unless the following are noted:
    a. CD4 count greater than 200 cells/mm^3 for greater than six (6) months; and
    b. HIV-1 RNA undetectable; and
    c. On stable anti-retroviral therapy greater than three (3) months; and
    d. No other complications from AIDS (eg, opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis, resistant fungal infections, Kaposi's sarcoma or other neoplasm); and
    e. Meeting all other criteria for liver transplantation; and
11. Serious cardiac or other ongoing insufficiencies that create an inability to tolerate transplant surgery; or
12. Serious conditions that are unlikely to be improved by transplantation as life expectance can be finitely measured.

- Liver retransplantation may be considered medically necessary in patients with:
  - primary graft non-function; or
  - hepatic artery thrombosis; or
  - chronic rejection; or
  - ischemic type biliary lesions after donation after cardiac death; or
  - recurrent non-neoplastic disease causing late graft failure

Services that do not meet the criteria of this policy will not be considered medically necessary. A Delaware participating, preferred or network provider cannot bill the member for the denied service unless: (a) the provider has given advance written notice, informing the member that the service may be deemed not medically necessary; (b) the member is provided with an estimate of the cost; and (c) the member agrees in writing to assume financial responsibility in advance of receiving the service. The signed agreement must be maintained in the provider's records. Out-of-network/non-participating providers and providers located outside of Delaware may be able to bill members if the service is denied.

Please refer to Medical Policy **S-121** for more information.

Allergy skin testing criteria revised

Effective Jan. 6, 2014, Highmark Delaware will revise the medical necessity criteria for Allergy Skin Testing as follows:

Allergy testing may be considered medically necessary in the diagnosis of allergies by ANY ONE of the following tests:

- Direct skin test with ANY ONE of the following techniques:
  - Percutaneous (scratch, prick, or puncture) up to 70 tests per patient per year (365 day period). Payment should not be made in excess of this limit except in extraordinary circumstances. Services exceeding this limitation are considered not medically necessary; or
  - Intracutaneous (intradermal) up to 70 tests per patient per year (365 day period) Payment should not be made in excess of this limit except in extraordinary circumstances. Services exceeding this limitation are considered not medically necessary; or
- Patch test (Application test) for diagnosing contact dermatitis; or
- Photo patch test for diagnosing a photo-allergy (e.g., photo-allergic contact dermatitis); or
- Bronchial challenge tests to diagnose ANY ONE of the following:
  - To identify new allergens for which skin or blood testing has not been validated; or
  - Skin testing is unreliable; or

- Oral challenge tests for any of the following:
    - Food or other substances (i.e., additives or preservatives); or
    - Drugs when ALL of the following are met:
        - An allergy to multiple classes of drugs within a drug category is suspected (i.e., allergic to penicillin, and cephalosporins);

      AND
        - There is no effective alternative drug; or
        - Treatment with that drug is essential.

Skin endpoint titration (SET) used in conjunction with immuno-therapy may be medically necessary with ANY ONE of the following criteria when there is potential for the specific allergen in question to produce a severe systemic allergic reaction or anaphylaxis:

- To determine a safe starting dose for testing; or
- To determine a safe starting dose for immuno-therapy.

Allergy testing methods with ANY ONE of the following are considered not medically necessary.

- Cytotoxic food testing; or
- Leukocyte histamine release (86343); or
- Provocative testing (e.g., Rinkel); or
- Sublingual (antigens prepared for sublingual administration); or
- Mucous membrane testing (e.g., direct nasal,ophthalmic).

Services that do not meet the criteria of this policy will not be considered medically necessary. A Delaware participating, preferred or network provider cannot bill the member for the denied service unless: (a) the provider has given advance written notice, informing the member that the service may be deemed not medically necessary; (b) the member is provided with an estimate of the cost; and (c) the member agrees in writing to assume financial responsibility in advance of receiving the service. The signed agreement must be maintained in the provider's records. Out-of-network/non-participating providers and providers located outside of Delaware may be able to bill members if the service is denied.

Please refer to Medical Policy **Z-26** Allergy Skin Tests for additional information.

Criteria added for treatment of the prostate

Highmark Delaware has updated its coverage criteria for Treatment of the Prostate. The new guidelines will become effective on Jan. 6, 2014.

ANY ONE of the following procedures may be considered medically necessary when used to treat prostate conditions:

- Cryoablation of the prostate may be considered medically necessary as treatment of clinically localized (organ-confined) prostate cancer when performed
    - As initial treatment; or
    - As salvage treatment of disease that recurs following radiation therapy; or
- Water-induced thermotherapy (WIT), also called thermourethral hot-water therapy of the prostate; or
- Transurethral needle ablation (TUNA) of the prostate; or
- Laser ablation of the prostate; or
- Transurethral resection of the prostate (TURP); or
- Open/laparoscopic prostatectomy; or
- Transurethral microwave thermotherapy (TUMT)

The following procedures will be considered as experimental/investigational:

- Subtotal prostate cryoablation in the treatment of prostate cancer; and
- High-intensity focused ultrasound (HIFU) ablation for the treatment for benign prostatic hyperplasia (BPH); and
- Placement of temporary prostatic stents for the treatment for BPH

Please refer to Medical Policy **S-97** for more information.

Additional criteria for small bowel/liver and multivisceral transplantation

Highmark Delaware is updating its coverage criteria for small bowel/liver and multivisceral transplantation. The new guidelines will become effective on Jan. 6, 2014.

Potential contraindications to solid organ transplant:

1. Known current malignancy, including metastatic cancer
2. Recent malignancy with high risk of recurrence
3. History of cancer with a moderate risk of recurrence
4. Systemic disease that could be exacerbated by immunosuppression
5. Untreated systemic infection making immunosuppression unsafe, including chronic infection
6. Other irreversible end-stage disease not attributed to intestinal failure
7. Psychosocial conditions or chemical dependency affecting ability to adhere to therapy

Small bowel/liver or multivisceral retransplant may be medically necessary after a failed primary small bowel/liver transplant or multivisceral transplant.

Small bowel transplant are considered experimental/investigational for adults with intestinal failure who are able to tolerate **total parenteral nutrition** (TPN). A participating, preferred, or network provider can bill the member for the non-covered service.

The following guidelines are used to process claims for eligible transplant procedures:

- Payment should be made for transplant services performed for a recipient who is a Plan member, including the removal of an organ from a living donor or cadaver. Payment is also made for the removal of an organ from a living donor who is a Plan member, even though the recipient is not. When only the recipient is a Plan member, donor benefits are limited to only those not provided or available to the donor from any other source. It will be necessary for the provider to submit medical records and/or additional documentation to determine coverage in this situation.

- Payment may be made under the recipient's Plan only when all other donor sources (eg, other insurance coverage, government program funding, etc.) have been exhausted. It will be necessary for the provider to submit medical records and/or additional documentation to determine coverage in this situation. Removal of an organ from a cadaver is payable only when the recipient is a Plan member.

- The above guidelines also apply to all preoperative testing. Once the donor has been established, payment may be made for the preoperative testing and medical examination for the donor in preparation for the surgery for the removal of the organ or tissue. The testing (eg, pathology tests, chest x-ray, and EKG) and medical examination are medically necessary prior to the administration of general anesthesia and/or major surgery.

- Based on the above guidelines, payment should be made for those services provided by the surgeon for the removal of the organ from the living donor or cadaver for the actual transplant.

- Testing performed to determine donor compatibility is classified as screening because the potential donor is asymptomatic. Liability for potential donor testing lies with the potential donor's health plan and is subject to contract provisions regarding such screening tests.

- Payment may not be made for the purchase price of human organs which are sold rather than donated to the recipient.

- Due to the nature of organ transplant surgery, team surgery is frequently involved.

See Medical Policy **S-12** for additional information.

Services that do not meet the criteria of this policy will not be considered medically necessary. A Delaware participating, preferred or network provider cannot bill the member for the denied service unless: (a) the provider has given advance written notice, informing the member that the service may be deemed not medically necessary; (b) the member is provided with an estimate of the cost; and (c) the member agrees in writing to assume financial responsibility in advance of receiving the service. The signed agreement must be maintained in the provider's records. Out-of-network/non-participating providers and providers located outside of Delaware may be able to bill members if the service is denied.

Please refer to Medical Policy **S-118** for more information.

Criteria changes for gradient compression garments

Highmark Delaware is updating its coverage criteria for Gradient Compression Garments. The new guidelines will become effective on Jan. 6, 2014.

Gradient compression garments/stockings may be considered medically necessary when prescribed by a physician, physician assistant, or certified registered nurse practitioner when ALL of the following are met:

ANY ONE of the following:
- Lymphedema; or
- Varicose veins (except spider veins); or
- Chronic venous insufficiency; or
- Venous stasis disease; or
- Venous valvular insufficiency; or
- Venous insufficiency; or
- Post thrombotic syndrome; or
- Venous ulcer (stasis ulcer), including any one of the following:
    - Edema
    - Venous
    - Lymph
    - Post traumatic
    - Post-surgical
    - Lipedema
- Angiodysplasia; or
- Prevention of thrombosis post-operatively; or
- Post sclerotherapy; or
- Documented thrombosis risk; or
- Venous eczema; or
- Lipodermatosclerosis

AND

ALL of the following:

- The garments(s) must be specifically ordered by a licensed physician, physician assistant, or certified registered nurse practitioner caring for an individual; and
- Documentation supporting medical necessity; and
- A written, signed and dated script must be received by the supplier before dispensing gradient compression garment or stocking; and
- Non-custom fit gradient compression garments/stockings are limited to three (3) pairs per six (6) month period.

Lymphedema compression garments for the extremities (e.g., sleeve, gauntlet, and stocking) may be medically necessary for the treatment of lymphedema when one conservative medical management has failed a four-week trial.

Custom-made gradient stocking**/**sleeve may be considered medically necessary when prescribed by a physician, physician assistant, or certified registered nurse practitioner when all of the following are met:

ANY ONE of the following:
- Lymphedema; or
- Varicose veins (except spider veins); or
- Chronic venous insufficiency; or
- Venous stasis disease; or
- Venous valvular insufficiency; or
- Venous insufficiency; or
- Post thrombotic syndrome; or
- Venous ulcer (stasis ulcer), including ANY ONE of the following:
    - Edema
    - Venous
    - Lymph
    - Post traumatic
    - Post-surgical
    - Lipedema
- Angiodysplasia; or
- Prevention of thrombosis post-operatively; or
- Post sclerotherapy; or
- Documented thrombosis risk; or
- Venous eczema; or
- Lipodermatosclerosis

AND

ANY ONE of the following:
- Failure for a prefabricated (off-the-shelf) garment to fit properly**;** or
- Fail to provide the therapeutic support**;** or
- Reinforced areas (eg, heels) or zippers alone are not unique and do not constitute a custom garment**;** or
- Documentation for diagnosis of obesity**;** or
- Documentation for diagnosis of venous insufficiency.

Lymphedema compression garments for the extremities (e.g., sleeve, gauntlet, and stocking) may be medically necessary for the treatment of lymphedema when one conservative medical management has failed a four-week trial.

Only a physician, physician assistant, or nurse practitioner can prescribe a compression gradient garment, compression gradient stocking, surgical stocking, or ready-made/off-the-shelf stocking.

Replacement custom-made gradient compression garments

Custom-made gradient compression stockings/sleeves replacement is considered medically necessary when ANY ONE of the following are met:

- Compression garment cannot be repaired; or
- Changes in physical condition (e.g., change in size, unusual drainage, wear that weakened the support).

No more than four replacement pressure gradient support stockings per year are considered medically necessary for wear.

Two pairs of custom-made gradient compression stockings/sleeves are considered medically necessary in the initial purchase. Once the initial trial phase is completed, only three pairs of pressure gradient support stockings per six months can be dispensed.

Please refer to Medical Policy **E-9** for more information.

Criteria established for Radium Ra 223 Dichloride for treatment of prostate cancer

Effective Jan. 6, 2014, Highmark Delaware will consider Radium Ra 223 Dichloride for treatment of prostate cancer (Xofigo®), medically necessary when all of the following indications are met:

- The individual has been diagnosed with castration-resistant prostate cancer (CRPC); and
- The individual has symptomatic bone metastases; and
- The individual has no known visceral metastatic disease.

Services that do not meet the criteria of this policy will not be considered medically necessary. A Delaware participating, preferred or network provider cannot bill the member for the denied service unless: (a) the provider has given advance written notice, informing the member that the service may be deemed not medically necessary; (b) the member is provided with an estimate of the cost; and (c) the member agrees in writing to assume financial responsibility in advance of receiving the service. The signed agreement must be maintained in the provider's records. Out-of-network/non-participating providers and providers located outside of Delaware may be able to bill members if the service is denied.

Please refer to Medical Policy **I-97** for more information.

Additional criteria for Single Photon Emission Computed Tomography (SPECT)

Highmark Delaware is updating its coverage criteria for Single Photon Emission Computed Tomography (SPECT). The new guideline will become effective on Jan. 6, 2014.

SPECT scans may be considered medically necessary for any of the following:

- Bone and joint conditions—to differentiate between infectious, neoplastic, avascular or a traumatic process
- Brain tumors—to differentiate between lymphomas and infections such as toxoplasmosis particularly in the immunosuppressed, or recurrent tumor vs. radiation changes, when positron emission tomography (PET) is not available
- Liver hemangioma—using labeled red blood cells to further define lesions identified by other imaging modalities
- Localization of abscess/infection/inflammation in soft tissues or cases of fever of unknown origin
- Neuroendocrine tumors (e.g., adenomas, carcinoid, pheochromocytomas, neuroblastoma, vasoactive intestinal peptide [VIP] secreting tumors, thyroid carcinoma, adrenal gland tumors)—using a monoclonal antibody (OctreoScan™ [Covidien, Hazelwood, MO]) or I-131 meta-iodobenzyl-guanidine (MIBG)
- Parathyroid imaging

- Renal—Dimercaptosuccinic acid (DMSA) scan to assess the status of kidney for scarring and function

SPECT scans are considered not medically necessary for the evaluation and management of cerebrovascular accident (CVA, stroke), subarachnoid hemorrhage, or transient ischemic attack.

SPECT scans are experimental/investigational for all other purposes, including, but not limited to:
- Attention deficit and hyperactivity disorder
- Chronic fatigue syndrome
- Colorectal carcinoma (e.g., used with the monoclonal antibody or IMMU-4 and CEA-Scan®)
- Dopamine transporter (DaT) scan for all indications
- Malignancies other than those listed as medically necessary
- Neuropsychiatric disorders without evidence of cerebrovascular disease
- Pervasive development disorders (PDD)
- Prostate carcinoma (e.g., used with the monoclonal antibody ProstaScint®, with or without fusion imaging with computed tomography or magnetic resonance imaging)
- Scintimammography for breast cancer
- SPECT/SISCOM for the preoperative evaluation of individuals with intractable focal epilepsy to identify and localize area(s) of epileptiform activity when other techniques designed to localize a focus is indeterminate

Please refer to Medical Policy **R-6** for more information.

Supporting documentation requirements revised for lymphedema therapy

Effective Jan. 6, 2014, Highmark Delaware will require the following supportive documentation be maintained in the medical record. The remainder of this policy is unchanged.

Supporting documentation requirements

ALL of the following documentation must be maintained in the medical record and be available upon request:
- A statement as to the ability of the patient/patient caregiver to follow through with the continuation of treatment on a long-term home treatment plan; and
- History and physical which addresses the cause of the lymphedema and any prior treatment.

  Components of the history are to include ALL of the following:
  - Age of onset; and
  - Primary or secondary lymphedema; and
  - Area(s) of involvement; and
  - Associated symptoms (including but limited to: a sense of heaviness, tightness, aching or discomfort in the limb; and restricted range-of-motion, commonly accompanying swelling); and
  - Medications– while none is directly associated with an increased risk of lymphedema, some are associated with edematous states (e.g., non-steroidal anti-inflammatory agents) or are contraindicated in the treatment of lymphedema (e.g., diuretics); and
  - Progression of symptoms; and
  - Measurements– a measurement of the body part/extremity must be documented prior to treatment. Clinical measurements of extremity girth are necessary to establish baseline and to track changes during treatment; and
  - Past medical history, including medical conditions associated with lymphedema, any prior travel, infections, surgery, or prior radiation therapy (RT); and
  - Family history; and
- Components of the physical exam should evaluate the vascular system, skin, and soft tissue, and palpation of the lymph nodes. If primary lymphedema is suspected, evaluation should include documentation of any physical signs or congenital anomalies associated with an inherited condition; and

- A report showing the progress of the therapy, including:
  - Measurements showing a reduction in size of the extremity; and
  - The response of the patient/patient caregiver to the education and their understanding and ability to take on some of the responsibilities of the treatment; and
  - The expected outcome of the treatment as well as the expected duration of treatment.

Services that do not meet the criteria of this policy will not be considered medically necessary. A Delaware participating, preferred or network provider cannot bill the member for the denied service unless: (a) the provider has given advance written notice, informing the member that the service may be deemed not medically necessary; (b) the member is provided with an estimate of the cost; and (c) the member agrees in writing to assume financial responsibility in advance of receiving the service. The signed agreement must be maintained in the provider's records. Out-of-network/non-participating providers and providers located outside of Delaware may be able to bill members if the service is denied.

Please refer to Medical Policy **Y-11** for more information.

Schnur Sliding Scale and possible link to calculator to assist in calculating body surface area for breast reduction surgery

Highmark Delaware has revised Medical Policy **S-28**, Cosmetic Surgery vs. Reconstructive Surgery, to include a different Schnur Sliding Scale and a link to a possible calculator, if needed, to assist in the calculation of body surface area for breast reduction surgery.

Minimum Weight of Breast Tissue Removed, per Breast, as a Function of Body Surface Area Schnur Sliding Scale

Body surface area (meters squared)	Minimum weight of tissue to be removed per breast (grams)
1.35	199
1.40	218
1.45	238
1.50	260
1.55	284
1.60	310
1.65	338
1.70	370
1.75	404
1.80	441
1.85	482
1.90	527
1.95	575
2.00	628
2.05	687
2.10	750
2.15	819
2.20	895
2.25	978
2.30 or greater	>= 1000

The appropriate amounts (in grams) of breast tissue must be anticipated for removal from at least one breast, which is based on the individual's total body surface area (BSA) in meters squared.

If preferred, there are several websites with calculators to assist in calculating body surface area, an example is http://www.globalrph.com/bsa2.htm.

Please refer to Medical Policy **S-28** for more information.

New computed tomography policy defines coverage for lung cancer screening

Highmark Delaware is creating a new policy defining coverage for Computed Tomography (CT) for Lung Cancer Screening. Medical Policy **X-58**, CT for Lung Cancer Screening, will be published and effective on Jan. 6, 2014.

Low-dose CT scanning, no more frequently than annually for three consecutive years, may be considered medically necessary as a screening technique for lung cancer in individuals who meet ALL of the following criteria:

- Individual has no signs or symptoms suggestive of underlying lung cancer which includes, but is not limited to the following: unexplained cough; hemoptysis; or unexplained weight loss of more than 15 pounds in the past year; and
- Individual is between 55-74 years of age; and
- There is at least a 30 pack/year history of cigarette smoking; and
- If the individual is a former smoker, that individual had quit smoking within the previous 15 years.

Low-dose CT scanning is considered experimental/investigational; and therefore not covered as a screening technique for lung cancer for all other indications.

CT is a radiographic imaging technique that can provide high quality three-dimensional images of the lungs during a single breath hold. Due to its speed and sensitivity in detecting small lung lesions, low-dose spiral CT scanning, a variation of standard CT imaging has been proposed as a screening test for lung cancer in high-risk individuals (e.g., smokers).

For additional information, please refer to Medical Policy **X-58**.

Islet cell transplantation criteria added to policy

Highmark Delaware is updating its coverage criteria for Islet cell transplantation. The new guidelines will become effective Jan. 6, 2014.

Pancreas islet transplantation may be considered medically necessary as an adjunct to the following:

- Total pancreatectomy in patients with chronic pancreatitis; or
- Near total pancreatectomy in patients with chronic pancreatitis.

The following guidelines are used to process claims for eligible transplant procedures:

- Payment should be made for transplant services performed for a recipient who is a Plan member, including the removal of an organ from a living donor or cadaver. Payment is also made for the removal of an organ from a living donor who is a Plan member, even though the recipient is not. When only the recipient is a Plan member, donor benefits are limited to only those not provided or available to the donor from any other source. It will be necessary for the provider to submit medical records and/or additional documentation to determine coverage in this situation.

- Payment may be made under the recipient's Plan only when all other donor sources (e.g., other insurance coverage, government program funding, etc.) have been exhausted. It will be necessary for the provider to

submit medical records and/or additional documentation to determine coverage in this situation. Removal of an organ from a cadaver is payable only when the recipient is a Plan member.

- The above guidelines also apply to all preoperative testing. Once the donor has been established, payment may be made for the preoperative testing and medical examination for the donor in preparation for the surgery for the removal of the organ or tissue. The testing (i.e., pathology tests, chest x-ray, and EKG) and medical examination are medically necessary prior to the administration of general anesthesia and/or major surgery.

- Based on the above guidelines, payment should be made for those services provided by the surgeon for the removal of the organ from the living donor or cadaver for the actual transplant.

- Testing performed to determine donor compatibility is classified as screening because the potential donor is asymptomatic. Liability for potential donor testing lies with the potential donor's health plan and is subject to contract provisions regarding such screening tests.

- Payment may not be made for the purchase price of human organs which are sold rather than donated to the recipient.

- Due to the nature of organ transplant surgery, team surgery is frequently involved. See Medical Policy Bulletin **S-12** for additional information.

Services that do not meet the criteria of this policy will not be considered medically necessary. A Delaware participating, preferred or network provider cannot bill the member for the denied service unless: (a) the provider has given advance written notice, informing the member that the service may be deemed not medically necessary; (b) the member is provided with an estimate of the cost; and (c) the member agrees in writing to assume financial responsibility in advance of receiving the service. The signed agreement must be maintained in the provider's records. Out-of-network/non -participating providers and providers located outside of Delaware may be able to bill members if the service is denied

Please refer to Medical Policy **S-144** for more information.

Uveal melanoma removed as indication for coverage

Highmark Delaware has removed uveal melanoma as a covered indication on Medical Policy **R-21**, Stereotactic Radiosurgery.

Bony lesions of the spine that have failed external beam radiation, recurring or previously irradiated cancers of the spine and spinal cord, and recurring or previously irradiated tumors of the head and neck with metastasis to other critical organs or structures have also been removed from Medical Policy **R-21**. These are covered indications found on Medical Policy **R-14**, Stereotactic Body Radiation Therapy (SBRT).

See Medical Policies **R-14** and **R-21** for additional information.

Coverage changes for tumor marker tests

Effective Jan. 6, 2014, Highmark Delaware will make revisions to Medical Policy **L-28**, Tumor Markers, to clarify criteria for bladder cancer monitoring. Also, additional criteria for Calcitonin, Thyroglobulin, Thyroglobulin antibody, Human Epidermal Growth Factor Receptor 2, and Early CDT-Lung for detection of lung cancer will be added. The revisions are as follows:

Breast cancer and gastric cancer tumor testing

Human epidermal growth factor receptor 2 (HER2) testing
Human Epidermal Growth Factor Receptor 2 (83950) testing is considered medically necessary for determining HER2 status of breast cancer, gastric cancer or gastroesophageal junction adenocarcinoma whose tumors overexpress the HER2 protein (HER2-positive cancer) and determining treatment. Either the immunohistochemistry (IHC)(88360 or 88361) or fluorescence in situ hybridization (FISH)(88365) may be used to determine HER2 tumor status.

Human Epidermal Growth Factor Receptor 2 (HER2) is considered not medically necessary in the diagnosis of cancer.

When performed for asymptomatic patients, tumor marker testing is considered screening and only covered by certain groups or programs as indicated in benefits.

Bladder cancer monitoring
The following urinary bladder cancer tumor markers:

- BTA Stat test, BTA TRAK;
- IMMUNOCYT;
- NMP22, NMP22 BLADDER CHEK; and
- UROVYSION;

may be considered medically necessary in any of the following conditions:

- follow-up of treatment for bladder cancer; or
- monitoring for eradication of bladder cancer; or
- recurrences after eradication.

Serum Calcitonin
Calcitonin (Ct)(82308) is a tumor marker essential for the diagnosis and follow-up of medullary thyroid cancer. Calcitonin serum test is considered medically necessary for the diagnosis and management of medullary thyroid cancer.

Calcitonin is considered experimental/investigational for any other indication other than listed above, and therefore, non-covered. A participating, preferred, or network provider can bill the member for the denied service.

Thyroglobulin Testing
Thyroglobulin (Tg) levels in the blood can be used as a tumor marker for certain kinds of thyroid cancer (particularly papillary or follicular thyroid cancer). Thyroglobulin is not produced by medullary or anaplastic thyroid carcinoma. Thyroglobulin testing (84432) is considered medically necessary for the diagnosis and management of thyroid cancer.

A thyroglobulin antibody (TgAb)(86800) test is typically ordered along with the thyroglobulin test to determine the validity of the thyroglobulin testing and is considered medically necessary.

Thyroglobulin testing and TgAb are considered experimental/investigational for any indication other than those listed above, and therefore, non-covered. A participating, preferred, or network provider can bill the member for the test.

Screening for Lung Cancer
Early CDT-Lung for detection of lung cancer (83520) is considered experimental/investigational. There is a lack of published peer-reviewed literature assessing the clinical utility of early CDT-lung cancer. Additional studies are needed to determine the role of this test in evaluating patients. A participating, preferred, or network provider can bill the member for the denied service.

Services that do not meet the criteria of this policy will not be considered medically necessary. A Delaware participating, preferred or network provider cannot bill the member for the denied service unless: (a) the provider has given advance written notice, informing the member that the service may be deemed not medically necessary; (b) the member is provided with an estimate of the cost; and (c) the member agrees in writing to assume financial responsibility in advance of receiving the service. The signed agreement must be maintained in the provider's records. Out-of-network/non-participating providers and providers located outside of Delaware may be able to bill members if the service is denied.

Please refer to Medical Policy **L-28** for more information.

Criteria added to solitary pancreas transplantation

Highmark Delaware is updating its coverage for Solitary Pancreas Transplantation. The new guidelines will become effective on Jan. 6, 2014.

A combined pancreas-kidney transplant may be considered medically necessary in insulin-dependent diabetic patients with uremia.

Please refer to Medical Policy **S-127** for more information.

Ankle-foot/knee-ankle foot orthosis coverage criteria revised

Effective Jan. 6, 2014, Highmark Delaware will revise the coverage criteria of ankle-foot/knee-ankle foot orthosis.

If a custom fabricated orthosis is provided but basic coverage criteria and the additional criteria for a custom fabricated orthosis are not met, the custom fabricated orthosis will be denied as not medically necessary. A participating, preferred, or network provider cannot bill the member for the denied service.

Concentric adjustable torsion style mechanisms used to assist knee joint extension are coded as L2999 and are covered; and therefore medically necessary for members who require knee extension assist in the absence of any co-existing joint contracture.

Concentric adjustable torsion style mechanisms used to assist ankle joint plantarflexion or dorsiflexion are coded as L2999 and are covered for members who require ankle plantar or dorsiflexion assist in the absence of any co-existing joint contracture.

Concentric adjustable torsion style mechanisms used for the treatment of contractures, regardless of any co-existing condition(s), is coded as E1810 and/or E1815, and is covered.

Claims for devices incorporating concentric adjustable torsion style mechanisms used for the treatment of any joint contracture and coded as L2999 will be denied as incorrect coding. A participating, preferred, or network provider can bill the member for the denied service.

All claims for devices that contain a concentric adjustable torsion style mechanism in the knee joint for any condition other than an assistive function to joint extension motion must be coded as Durable Medical Equipment using code E1810—dynamic adjustable knee extension/flexion device. If a concentric adjustable torsion style mechanism in the knee joint is used solely to provide an assistive function for joint extension, it must be coded as L2999.

All claims for devices that contain a concentric adjustable torsion style mechanism in the ankle joint for any condition other than an assistive function to joint plantar- or dorsiflexion motion must be coded as Durable Medical Equipment using code E1815—dynamic adjustable ankle extension/flexion device. If a concentric

adjustable torsion style mechanism in the ankle joint is used solely to provide an assistive function for joint plantar– or dorsiflexion, it must be coded as L2999.

Claims for devices that contain a concentric adjustable torsion style mechanism in the knee or ankle joint and that are being used to treat any condition other than an assistive function to joint extension motion are not covered under the braces benefit and will be denied as incorrect coding when billed using code L2999. A participating, preferred, or network provider can bill the member for the denied service.

Code L4205—Repair of orthotic device, labor components, per 15 minutes—may only be billed for time involved with the actual repair of an orthosis or for medically necessary adjustments made more than 90 days after delivery. Code L4205 must not be used to bill for time involved with other professional services including, but not limited to:

- Evaluating the member
- Taking measurements, making a cast, making a model, use of CAD/CAM
- Making modifications to a prefabricated item to fit it to the individual member
- Follow-up visits
- Making adjustments at the time of or within 90 days after delivery

Suppliers must distinguish between repair and replacement of an orthosis. When an orthotic is replaced, there is no separate billing for the above services because reimbursement for these services is included in the allowance for the replacement item.

Documentation requirements have also been added. This information specifically pertains to:

- Prescription (order) requirements
- Medical record information
- Proof of delivery
- Repair/replacement

Language was added specifying that a detailed written order (DWO) must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving the completed DWO, the item will be denied as not medically necessary.

For custom-fabricated orthoses, there must be documentation in the supplier's records to support the medical necessity of that type device rather than a prefabricated orthosis. This information does not have to be routinely sent in with the claim, but must be available upon request.

Services that do not meet the criteria of this policy will not be considered medically necessary. A Delaware participating, preferred or network provider cannot bill the member for the denied service unless: (a) the provider has given advance written notice, informing the member that the service may be deemed not medically necessary; (b) the member is provided with an estimate of the cost; and (c) the member agrees in writing to assume financial responsibility in advance of receiving the service. The signed agreement must be maintained in the provider's records. Out-of-network/non-participating providers and providers located outside of Delaware may be able to bill members if the service is denied.

Please refer to Medical Policy **O-24** for additional information.

Policy name change for fetal nuchal translucency

Highmark Delaware has revised the title of Medical Policy **X-51**, Fetal Nuchal Translucency. The policy will now be called First Trimester Screening for Fetal Aneuploidy and will be effective Jan. 6, 2014.

Additionally, the following verbiage will be removed from the policy regarding the timeframe for blood work collected:

- In these cases, the fetal nuchal translucency study in the first trimester is eligible when performed in conjunction with and no longer than seven days before or after the maternal serum markers.

See Medical Policy **X-51** for additional information.

Paravertebral facet joint nerve block coverage criteria revised

Effective Dec. 30, 2013, Highmark Delaware will revise the coverage criteria of paravertebral facet joint nerve blocks as follows:

Paravertebral facet joint nerve blocks (64490, 64491, 64492, 64493, 64494, and 64495) are considered medically necessary when ALL of the following criteria are met:

- Back pain for at least three months and has not responded to conservative therapy (i.e., physical/chiropractic therapy, activity modification, non-steroidal anti-inflammatory drugs, muscle relaxants, and non-narcotic analgesics); and
- Pain is interfering with functional activities; and
- Pain is non-radicular (radiculopathy [a disorder of spinal nerve roots] ruled out by MRI in patients with complaints of pain radiating to upper/lower extremities); and
- No prior history of vertebral fusion at the levels being treated; and
- Pain exacerbated by extension and prolonged standing/sitting and is relieved by rest; and
- Other treatable causes of pain (i.e., tumors, infection) have been ruled out; and
- Paravertebral facet joint nerve blocks meets the criteria for ANY ONE of the injections below:
    1. A diagnostic paravertebral facet joint nerve block being performed to determine chronic pain is of facet joint origin;
       OR
    2. Therapeutic paravertebral facet joint nerve block performed to treat pain when ALL of the following criteria are met:
        - A diagnostic paravertebral facet joint nerve block provided at least 50% pain relief; and
        - Therapeutic blocks performed no more often than four injections per level, per year.

Services that do not meet the criteria of this policy will not be considered medically necessary. A Delaware participating, preferred or network provider cannot bill the member for the denied service unless: (a) the provider has given advance written notice, informing the member that the service may be deemed not medically necessary; (b) the member is provided with an estimate of the cost; and (c) the member agrees in writing to assume financial responsibility in advance of receiving the service. The signed agreement must be maintained in the provider's records. Out-of-network/non-participating providers and providers located outside of Delaware may be able to bill members if the service is denied.

Ultrasound guidance for facet joint injections (0213T, 0214T, 0215T, 0216T, 0217T, and 0218T) is considered experimental/investigational because there is insufficient clinical evidence of its safety and effectiveness. A participating, preferred, or network provider can bill the member for the denied service.

Please refer to Medical Policy **Z-61** for more information.

Quantitative measurement of serum antibodies to Infliximab considered experimental/investigational

Effective Dec. 30, 2013, Highmark Delaware considers quantitative measurement of serum antibodies to infliximab, also referred to as human antichimeric antibodies (HACA), as experimental/investigational.

Although measurements of serum levels of infliximab and antibodies to infliximab (human anti-chimeric antibodies [HACA (eg, the Anser IFX test [Prometheus Lab]) may aid physicians in determining the dose of infliximab and guide infusion intervals, the testing is considered experimental/investigational because the clinical value of these measurements for individuals receiving infliximab therapy has not been established.

A participating preferred, or network provider can bill the member for the denied testing.

Please refer to Medical Policy **I-28** for more information.

Habilitative care now covered for multiple services

Highmark Delaware now covers habilitative care for multiple services. The following revised medical policies will be effective Jan. 1, 2014 and published Jan. 6, 2014:

- Medical Policy V-16, Speech Therapy
- Medical Policy Y-1, Physical Medicine
- Medical Policy Y-2, Occupational Therapy

Please use procedure code **S8990** for all habilitative services as defined below.

HABILITATIVE SERVICES ordered by a professional provider to promote the restoration, maintenance, or improvement in the level of function following disease, illness, or injury are covered according to the member's individual or group customer benefit. Habilitative Care also includes therapies to achieve functions or skills never acquired due to congenital and developmental anomalies.

Spinal manipulation is not considered a habilitative service.

CODES

New codes

The following new code and modifier will be available for your reporting purposes on Oct. 1, 2013.

Code	Terminology	Effective
AO	Alternate payment method declined by provider of service	10/01/2013
G9187	Bundled Payments for Care Improvement Initiative home visit for patient assessment performed by a qualified health care professional for individuals not considered homebound including, but not limited to, assessment of safety, falls, clinical status, fluid status, medication reconciliation/management, patient compliance with orders/plan of care, performance of activities of daily living, appropriateness of care setting. (For use only in the Medicare-approved Bundled Payments for Care Improvement Initiative.) May not be billed for a 30-day period covered by a transitional care management code.	10/01/2013